Applicant: Gary Gomringer et al. Attorney's Docket No.: 10527-417001 / 01-135

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## <u>REMARKS</u>

Applicants have amended claim 27, and have added new claims 40-47.

Applicants note that the Examiner has initialed and returned sheet 2 of 2 of the Information Disclosure Statement filed with the U.S. Patent and Trademark Office on October 31, 2001. Applicants have enclosed a copy of sheet 1 of 2 of the October 31, 2001 Information Disclosure Statement with this Reply, and request that the Examiner confirm receipt of the sheet.

Claims 22-29 and 40-47, of which claims 22, 27, and 43 are independent in form, are presented for examination.

## Claim Rejections - 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a)

The Examiner has rejected claims 27-29 as either anticipated by U.S. Patent No. 6,334,871 (Dor) under 35 U.S.C. § 102(b), or obvious over Dor under 35 U.S.C. § 103(a).

As amended, claims 27-29 recite a stent comprising a radiopaque rivet including a shaft that has a length of from 0.004 inch to 0.007 inch. Dor does not describe or suggest the stent recited in claims 27-29. Dor describes stents that are marked by inserting rivets with a higher radiopacity than the stents through the ends or edges of the stents. (See, e.g., Dor, col. 2, lines 15-18.) Dor does not describe or suggest that the rivets would have a shaft with a length of from 0.004 inch to 0.007 inch, or provide any dimensions (such as length) for the rivets. Thus, Applicants request that the rejection of claims 27-29 be withdrawn.

Applicants note that the Examiner has stated that, "[R]ivet 8 for example, can be made to have a smaller shaft diameter for inserting into hole 2 before compressing rivet 8 to create cone heads containing in beveled edges 17 as this process is conventional and well-known in the art." (January 21, 2004 Office Action, pages 2-3.) If the Examiner is relying on official notice for this statement, then Applicants request that the Examiner provide documentary evidence so that Applicants can address the evidence. (See MPEP 2144.03.)

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## Claim Rejections - 35 U.S.C. § 103(a)

The Examiner rejected claims 22-26 as unpatentable over Dor in view of U.S. Patent No. 3,869,956 (Breer). But there is no motivation to combine Dor and Breer. Dor describes stents that are marked by radiopaque rivets, while Breer has nothing to do with stents or any other medical devices. Instead, Breer describes fasteners that are used to join "aluminum components of high performance aircraft structures." (See, e.g., Dor, col. 2, lines 15-18, and Breer, col. 1, lines 4-7.) A person of ordinary skill in the art would not combine an aircraft component reference with a stent reference to arrive at the stent of claims 22-26.

Furthermore, assuming but not conceding that a person of ordinary skill in the art would combine an aircraft component reference with a stent reference, that person would not combine Dor with Breer, at least because Dor describes using a relatively soft rivet in a relatively hard material, while Breer describes using a relatively hard rivet in a relatively soft material.

Dor describes a stent within which are inserted radiopaque rivets. (See, e.g., Dor, col. 2, lines 15-20.) The rivets are made of, for example, gold, gold alloy, tantalum, tantalum alloy, platinum, platinum alloy, or titanium. (See, e.g., Dor, col. 2, lines 19-20 and col. 5, lines 25-28.) Dor suggests using harder materials for the stent body than for the rivets. For example, Dor notes that, "The radiopaque markers described below are designed for stents produced from a material that is not sufficiently radiopaque to be seen through the use of fluoroscopy, e.g., a material such as Stainless Steel 316L, nitinol, or a cobalt chromium alloy." (Dor, col. 2, lines 5-9.) Furthermore, Dor teaches away from making a stent body out of a relatively soft material. For example, Dor states in his Background section that, "a disadvantage of [a prior art stent made from a radiopaque material such as tantalum] is that tantalum is a relatively soft material and it is, therefore, necessary to use more of this metal to achieve sufficient support from the stent." (Dor, col. 1, lines 51-57.) Thus, upon reading Dor, one of skill in the art would be motivated to use a stent body made of a relatively hard material and rivets made of a relatively soft material.

Breer, on the other hand, addresses a problem that can occur from using relatively hard rivets in a relatively soft material. Specifically, Breer focuses on using special high strength fasteners to hold aluminum components together. (Breer, col. 1, lines 4-13.) Breer states that,

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"the rivet material is much harder than the aluminum structure which it joins." (Breer, col. 2, lines 19-21.) As a result, if the rivet is upset, it can cause distortion in the aluminum. (See, e.g., Breer, col. 2, lines 21-27.) Breer first notes that a washer has been used in the past to help distribute compressive forces and thereby reduce distortion caused by the rivet. (See, e.g., Breer, col. 2, lines 51-55.) Breer then describes his rivet system, which includes a right cylindrical pin 20 with a collar 21. (See Breer, col. 2, lines 65-67.) Breer explains that his rivet system has the benefit of providing "control of rivet expansion-and-upset", which can thereby "enable[] the use of very high strength steel and nickel base alloys for the rivet material in aluminum structures." (Breer, col. 4, lines 1-3 and 29-32, emphasis added.)

A person of ordinary skill in the art would not be inclined to use the washer described in Breer in the stent described in Dor, because the person of ordinary skill in the art would not be motivated to combine Breer with Dor. Accordingly, Applicants request that the rejection of claims 22-26 be withdrawn.

## New Claims

Applicants have added new claims 40-47. New claims 40-42 depend from claim 22, and are patentable for at least the reasons described above. New claims 43-47 recite a stent comprising a rivet having a first end with a diameter of from 0.0038 inch to 0.0058 inch. Neither Dor nor Breer describes or suggests the rivet recited in new claims 43-47. Thus, Applicants believe that claims 40-47 are in condition for allowance.

Applicants believe that claims 22-29 and 40-47 are in condition for allowance, which action is requested.

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Respectfully submitted,

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Date: MAY 11, 2004

Tu N. Nguyen Reg. No. 42,934

Fish & Richardson P.C. 225 Franklin Street Boston, MA 02110-2804 Telephone: (617) 542-5070 Facsimile: (617) 542-8906

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